

EXHIBIT 4

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., PELVIC) Master File No.
REPAIR SYSTEM PRODUCTS) 2:12-MD-02327
LIABILITY LITIGATION) MDL 2327

5 THIS DOCUMENT RELATES TO
6 PLAINTIFFS:

7 Diane Kropf
Case No. 2:12-cv-01202 JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE
8 Judy Williams
Case No. 2:13-cv-00657
9 Myra Byrd
10 Case No. 2:12-cv-00748
11 Angela Coleman
Case No. 2:12-cv-01267
12 Susan Thamen (Reeves)
13 Case No. 2:12-cv-00279
14 Donna Zoltowski
Case No. 2:12-cv-00811
15
16

17 DEPOSITION OF JOSEPH M. CARBONE, M.D.
18 GENERAL PROLIFT
19 Wednesday, March 16, 2016
20 Danville, Virginia
21 9:20 p.m.
22

23 Reported by: Karen K. Kidwell, RMR, CRR, CLR
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1 which you don't have a list for, are randomized
2 controlled trials? Did you do that analysis?

3 A. I did not. But I didn't specify that
4 these pelvic floor repair system studies were
5 randomized control, so please don't read into that in
6 my sentence.

7 Q. Do you know what time frame is being
8 referenced when you make this statement?

9 A. Since its inception till now.

10 Q. So when do you believe is its date of
11 inception?

12 A. With the research from the -- the study
13 group from the European study group.

14 Q. So any study that predates that study
15 would not be included in this list of 100 studies?

16 A. I'm sorry?

17 Q. Any study which predates --

18 A. The European --

19 Q. -- the European study would not be
20 included in the over 100 studies you claim have been
21 done with Prolift?

22 A. It probably wouldn't, no.

23 Q. Do you know of any changes that have been
24 made to the design of the Prolift since it was
25 launched in March of 2005?

1 MR. ROSENBLATT: Object to form.

2 THE WITNESS: To the Prolift? I mean,
3 you're talking about Prolift. There's been
4 Prolift M.

5 BY MR. FAES:

6 Q. No. I'm talking about the Prolift.
7 Forget about the Prolift M.

8 A. See, that's what I'm saying. There have
9 been design changes with respect to the Prolift and
10 the Prolift M and there was some other issues. So,
11 in answer to your question, there have been design
12 changes that I'm aware of. So, yes, Prolift to
13 Prolift M. Yes, that's the design change.

14 Q. Setting aside the Prolift M --

15 A. Okay. Go ahead.

16 Q. -- are you aware of any changes that have
17 been made to the Prolift since it was launched in
18 March of 2005 in the United States?

19 A. In March of 2005? Design changes?

20 Q. Correct.

21 A. Not that I'm aware of.

22 Q. So it's fair to say, if there were design
23 changes made after March of 2005, you wouldn't be
24 aware of how those changes might affect the safety or
25 efficacy of the device because you don't know what

1 those changes are?

2 A. No, I would be aware. I disagree with
3 that completely. And because -- I would be aware
4 because they would be included in the random -- in
5 the high-level research that's out there regarding
6 the TVT Prolift -- I'm sorry; I keep saying TVT
7 because I just went through TVT -- the Gynecare
8 Prolift product that's been included in the
9 literature.

10 I mean, the bottom line is, whether I know
11 whether there's been a product change or a design
12 change, as you say, that design change would still be
13 included in the literature, the body of literature
14 that I've reviewed, the high-level body of literature
15 that I've reviewed. So whether or not I know -- I
16 would know whether it affects the safety or efficacy
17 because it would show up in the literature that I've
18 reviewed.

19 Q. But since you don't know what design
20 changes occurred and when they occurred, you wouldn't
21 be able to do an analysis of the data from, say, the
22 time before the design changed and the time after?

23 A. Well, fortunately --

24 MR. ROSENBLATT: Object to form. Lack of
25 foundation about design changes to Prolift.

1 THE WITNESS: Can I answer?

2 MR. ROSENBLATT: Yeah, you can answer.

3 THE WITNESS: Fortunately, the data seems,
4 at least for the high-level studies, seems
5 relatively consistent. So it's not a matter of
6 whether I have to know when the design -- I
7 mean, let's say, in X period, right, the design
8 changed. Well, the results previous to the
9 design change and the results after the design
10 change seem to be relatively consistent.

11 So I don't understand whether what your --
12 what clinical relevance -- I guess, what I'm
13 saying to you is what clinical relevance it has
14 as to whether I know when the design change
15 happened so long as I know the body of
16 literature, which is robust, regarding the
17 safety and efficacy of the Gynecare Prolift
18 product.

19 BY MR. FAES:

20 Q. Well, how can you say that the data
21 remains consistent when you don't know what time
22 periods to analyze?

23 A. From -- wait. Go ahead. Go ahead.
24 Object.

25 MR. ROSENBLATT: Object to form.

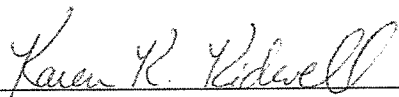
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I, Karen K. Kidwell, RMR, CRR, in and for
the Commonwealth of Virginia, do hereby certify that
there came before me on Wednesday, March 16, 2016, the
person hereinbefore named, who was by me duly sworn to
testify to the truth and nothing but the truth of his
knowledge concerning the matters in controversy in this
cause; that the witness was thereupon examined under
oath, the examination reduced to typewriting under my
direction, and the deposition is a true record of the
testimony given by the witness.

I further certify that I am neither attorney
or counsel for, nor related to or employed by, any
attorney or counsel employed by the parties hereto or
financially interested in the action.

This the 18th day of March, 2016.



Karen K. Kidwell, RMR, CRR
Notary Public #7625774

My Commission Expires: 9/30/2019